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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,138	12/12/2000	J. Gregor Sutcliffe	TSRI 548.1 DIV.1	7388

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/30/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/735,138

Applicant(s)

SUTCLIFFE ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-15, 30-35 and 60-62 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 14, 30, 34 and 61 is/are allowed.
- 6) ☒ Claim(s) 10-13, 15, 32, 33, 35, 60, and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 8/6/02 is: a) ☒ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other:

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### DETAILED ACTION

The response filed November 12, 2002 (Paper No. 12) has been entered. Applicants' election without traverse of Group I, Claims 8, 10-15, 30, 32-35, and 60-62 in Paper No. 12 is acknowledged. The elected invention is drawn to a rat hypocretin polypeptide having the amino acid sequence of SEQ ID NO: 1 and fragments thereof, and a pharmaceutical composition comprising a rat hypocretin polypeptide having the amino acid sequence of SEQ ID NO: 1 or fragments thereof.

Claims 8-15, 30-35, and 60-62 are pending in the instant application.

Claims 9 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 12.

Accordingly, Claims 8, 10-15, 30, 32-35, and 60-62 are examined herein.

Claims 10, 15, 32, 35, 60, and 61 embrace the inventions of Groups I and II. Thus, Claims 10, 15, 32, 35, 60, and 61 will be examined only to the extent that they encompass the elected subject matter.

### *Drawings*

The proposed drawing correction filed August 6, 2002 (Paper No. 10) is approved by the Examiner. The Examiner finds support for the proposed corrections to the mouse nucleotide sequence (3<sup>rd</sup> line in Fig. 5A) in SEQ ID NO: 4 of the Sequence Listing originally filed with this application on 12/12/00.

### *Specification*

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See the specification at page 74, line 25.

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Appropriate correction is required.

*Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-13, 15, 32, 33, 35, 60, and 62 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims cover a variety of fragments of the polypeptide of SEQ ID NO: 1. However, the claimed fragments are not supported by either a specific and substantial asserted utility or a well-established utility because the specification fails to disclose a utility for fragments other than the amidated hcr2 peptide (SEQ ID NO: 9) and neither the specification as-filed nor any art of record disclose or suggest an activity for these polypeptide fragments such that any utility would be well-established for the claimed polypeptide fragments.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 15, 32, 33, 35, 60, and 62 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The disclosure only presents one skilled in the art with an invitation to experiment.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 15, 32, 35, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 15, 32, 35, and 60 are indefinite in so far as they encompass non-elected subject matter. The elected invention is drawn to a rat hypocretin polypeptide having the amino acid sequence of SEQ ID NO: 1 and fragments thereof, and a pharmaceutical composition comprising a rat hypocretin polypeptide having the amino acid sequence of SEQ ID NO: 1 or fragments thereof. However, these claims recite SEQ ID NO: 2 and fragments of SEQ ID NO: 2, which is non-elected subject matter. Thus, the metes and bounds of the claims are not clearly set forth.

#### *Conclusion*

Claims 8, 14, 30, 34, and 61 are allowable. In Example 7 the specification discloses that SEQ ID NO: 9 (the peptide designated hcr2) suppressed food intake by 40% over the 2 hours following intracerebroventricular administration of 5  $\mu$ g of the amidated hcr2 peptide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3388.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER